

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)-
1986**

This medicine is dispensed with a doctor's prescription only

Tariol Topical gel

Active ingredients:

Each 1 gram contains:

calcipotriol (as monohydrate) 50 mcg/g

betamethasone (as dipropionate) 0.5 mg/g

Inactive ingredients and allergens: See section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Tariol is used for local treatment of psoriasis of the scalp and for the treatment of mild to moderate psoriasis vulgaris of other body areas in adults 18 years of age and older.

Therapeutic group:

Calcipotriol - a synthetic derivative of a vitamin D used for external treatment of psoriasis.

Betamethasone - a synthetic corticosteroid.

Psoriasis is caused by the skin cells being produced too quickly, which causes redness, formation of scales and thickening of the skin.

Calcipotriol helps control the rate of skin cell formation and betamethasone reduces inflammation.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients (calcipotriol, betamethasone) or to any of the other ingredients in this medicine (see section 6).
- You have problems with calcium levels in the blood (ask the doctor).
- You have certain types of psoriasis: erythrodermic, exfoliative or pustular, ask the doctor.
- As Tariol contains a strong steroid **do not** use it on skin affected by:
 - skin infections caused by viruses (e.g. cold sores or chicken pox)
 - skin infections caused by a fungus (e.g. athlete's foot or ringworm)
 - skin infections caused by bacteria

- skin infections caused by parasites (e.g. scabies)
- tuberculosis
- red rash around the mouth (perioral dermatitis)
- thin skin, easily damaged veins, stretch marks
- ichthyosis (dry skin with fish-like scales)
- acne (pimples)
- severe flushing or redness of the skin on the face (rosacea)
- ulcers or broken skin

Special warnings about using this medicine

Before treatment with Tariol, tell your doctor if:

- You are using other medicines that contain corticosteroids, as you may get side effects.
- You have used this medicine for a long time and plan to stop (as there is a risk your psoriasis will get worse or "flare up" when steroids are stopped suddenly).
- You suffer from diabetes (as your blood sugar/glucose level may be affected by the steroid).
- Your skin becomes infected, as you may need to stop your treatment.
- You have a certain type of psoriasis called guttate psoriasis.
- You experience blurred vision or other visual disturbances.
- Avoid use on more than 30% of your body or using more than 15 grams per day.
- Avoid using under a bathing cap or bandages as it increases the absorption of the steroid.
- Avoid use on large areas of damaged skin, mucous membranes or in skin folds (groin, armpits, under breasts) as it increases the absorption of the steroid.
- Avoid use on the face or genitals as these areas are very sensitive to steroids.
- Avoid prolonged exposure to the sun, extended use of solarium (tanning bed for example) or any other form of light treatment.

Do not smoke or move close to an open flame - risk of severe burns. Fabric (clothing, bedding, dressings, etc.) that has been in contact with this medicine burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce build-up of the medicine but not completely remove it.

Children and adolescents

This medicine is not intended for use in children below 18 years of age.

Drug interactions:

If you are taking or recently taken other medicines including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before using this medicine.

If the doctor has agreed that you can use Tariol while breastfeeding, take care and do not apply the gel to the breast area.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The medicine is intended for use on skin.

Instructions for use

- Use the gel only on areas affected by psoriasis and do not use on skin which is not affected by psoriasis.
- Shake the bottle before use and remove the cap.
- Apply the gel to a clean finger or directly to the area affected by psoriasis.
- Apply the gel to the affected area with your fingertips, and rub it in gently until the area affected by psoriasis is covered by a thin layer of gel.
- Do not bandage, tightly cover or wrap the treated area.
- Wash your hands well after using Tariol in order to prevent accidentally spreading the gel to other areas of your body (especially the face, mouth and eyes).

Do not worry if some gel accidentally gets on healthy skin near your psoriasis, but wipe it off if it spreads beyond the treatment area.

In order to achieve optimal results, it is recommended not to take a shower immediately after use of Tariol. After use, avoid contact with textiles which are easily stained by grease (e.g. silk).

If you have scalp psoriasis:

Before applying the gel to the scalp, comb your hair to remove any loose scales. Tilt your head to prevent the gel from running onto your face. Parting your hair before using Tariol may help. Apply the gel to the affected area with your fingertips, and rub it in gently.

Washing your hair before using Tariol is not necessary.

Directions for use:

- Shake the bottle before use.
- Apply a drop of Tariol to fingertip.
- Apply directly to the affected scalp area and gently rub the gel on to the skin.
- Depending on the affected area, 1-4 grams (up to 1 teaspoon) is generally sufficient for treatment of the scalp.

In order to achieve optimal results, it is recommended that the hair not be washed immediately after use of Tariol. Let Tariol remain on the scalp during the night or day.

When washing hair after use, the following instructions might be useful:

- Use a mild shampoo on dry hair, especially to those areas where the gel was used.
- Leave the shampoo on the scalp for a couple of minutes before washing.
- Wash your hair as usual.

If necessary, repeat the hair-washing steps once or two more times.

Do not exceed the recommended dose.

Duration of treatment

- Do not swallow! For external use only.
- It may be more convenient to use the gel in the evening.

- The initial treatment period is 4 weeks for the scalp area and 8 weeks for other body areas. The doctor can decide on a different duration of treatment. The doctor may also decide on repeated treatment.
- Do not use on more than 30% of the body surface or more than 15 grams of Tariol daily.

If you use other calcipotriol containing medicines, do not use more than 15 grams per day for the total dose of calcipotriol containing medicines, and the treated area should not exceed 30% of the total body surface.

What should I expect when using Tariol?

Most patients see results after 2 weeks of starting treatment, even if the psoriasis is not completely cleared by this time.

If you used more Tariol than you should Contact your doctor if you have used more than 15 grams in one day. Excessive use can cause a problem with your blood calcium levels, which usually return to normal levels after cessation of the treatment. The doctor may need to carry out blood tests to check that using too much gel has not caused a problem with calcium levels in the blood. Excessive and prolonged use can also cause the adrenal glands to stop working properly (the adrenal glands are found near the kidneys and produce hormones).

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the designated time, do not take a double dose to make up for the forgotten dose. Adhere to the treatment as recommended by your doctor.

If you stop using the medicine Even if your condition has improved, do not stop treatment with the gel without consulting the doctor.

It may be necessary for you to stop use gradually, especially if you have used the gel for a long time.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using **Tariol** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

Contact your doctor immediately or as soon as possible if the following side effects occur. You may have to stop treatment.

Uncommon side effects (effects that appear in 1-10 in 1,000 users):

- Worsening of psoriasis. If your psoriasis gets worse, tell your doctor as soon as possible.

Some serious side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in Tariol. Contact your doctor as soon as possible if one or more of the serious side effects occur.

These side effects are more likely to happen after long-term use, or use in skin folds (e.g. groin, underarm or under breasts), use under occlusion or use on large areas of skin.

The side effects include the following:

- The adrenal glands may stop working properly. Symptoms include tiredness, depression and anxiety.
- Cataracts (signs are cloudy and foggy vision, difficulty seeing at night and sensitivity to light) or an increase in pressure inside the eye (signs are eye pain, redness of the eye, decreased or cloudy vision).
- Infections (because your immune system, which fights infections, may be suppressed or weakened).
- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, **stop taking Tariol and contact your doctor as soon as possible.**
- Impact on the metabolic control of diabetes (if you have diabetes, you may experience fluctuations in the blood glucose levels).

Serious side effects known to be caused by the active ingredient calcipotriol in the medicine:

- Allergic reactions with deep swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and trouble breathing may occur. If you have an allergic reaction, **stop taking Tariol and contact a doctor immediately or go to the hospital emergency room.**
- Use of this medicine may cause the level of calcium in your blood or urine to increase (usually when too much gel has been used). Signs of a high level of calcium in the blood are: increased urination, constipation, muscle weakness, confusion and coma. **This can be serious, and you should contact a doctor immediately.** However, when the treatment is stopped, the levels of calcium return to normal.

Less serious side effects

The following less serious side effects have been reported for Tariol.

Common side effects (effects that appear in 1-10 out of 100 users):

- Itching

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):

- Eye irritation
- Burning sensation of the skin
- Skin pain or irritation
- Inflammation or swelling of the hair follicles (folliculitis)
- Rash with inflammation of the skin (dermatitis)
- Redness of the skin due to widening of the small blood vessels (erythema)
- Acne (pimples)
- Dry skin
- Rash
- Pustular rash
- Infection of the skin

Rare side effects (effects that appear in 1-10 out of 10,000 users):

- Allergic reactions
- Stretch marks
- Skin exfoliation
- Rebound effect: worsening of symptoms/psoriasis after completion of treatment

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- White or grey hair may temporarily change to a yellowish color at the application site when used on the scalp
- Blurred vision

Less serious side effects caused by the active ingredient, betamethasone, in the medicine, especially after prolonged use, include the following side effects. Contact the doctor as soon as possible if you notice one or more of them:

- Thinning of the skin
- Appearance of surface veins or stretch marks
- Changes in hair growth
- Red rash around the mouth (perioral dermatitis)
- Skin rash with inflammation or swelling (allergic contact dermatitis)
- Small golden-colored gel-filled bumps (colloid milia)
- Lightening of skin color (depigmentation)
- Inflammation or swelling of the hair root (folliculitis)

Less serious side effects caused by the active ingredient calcipotriol in the medicine include:

- Dry skin
- Sensitivity of the skin to light resulting in a rash
- Eczema
- Itching
- Skin irritation
- Burning and stinging sensation of the skin
- Redness of the skin due to widening of the small blood vessels (erythema)
- Rash
- Rash with inflammation of the skin (dermatitis)
- Worsening of psoriasis

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store in the outer carton in order to protect from light. Do not refrigerate. Store at a temperature below 25°C. Can be used up to 6 months after first opening.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Mineral oil, hydrogenated castor oil, polyoxypropylene stearyl ether EP (PPG-11).

What the medicine looks like and contents of the pack:

An almost clear gel.

Approved pack sizes: A pack that contains one bottle of 30 grams, a pack that contains one bottle of 60 grams and a pack that contains two bottles of 60 grams each (2X60 g).

Not all pack sizes may be marketed.

Manufacturer's name and address: Taro Pharmaceuticals Inc., 130 East Drive, Brampton, Ontario, Canada, L6T 1C 1

License holder's name and address:

Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761.

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